PROGRAM OVERVIEW:

Within Pharmaceutical and Biotechnology manufacturing operations, maintaining a rigorous level of quality assurance is of the utmost importance. Outside of the strenuous and ever increasing FDA and international regulatory standards, there is also the need to maintain the highest possible level of product quality. As corporations work to adapt to complex products, along with ever evolving regulatory guidance, learning from other organizations that have successfully grappled with these issues is of the utmost importance. This program will provide the pharmaceutical and biotechnology industries an open forum for discussion and debate amongst leading organizations on how to maintain the highest level of quality within manufacturing facilities.

With a number of high-profile cases of non-compliance with serious consequences, the FDA is continuing to increase their surveillance and scrutiny of manufacturing facilities. Another area of considerable concern for industry are the lengths that need to be taken to maintain quality measures in facilities that are not owned by the manufacturer, but that are contracted out to manufacture part of all of the therapy. Implementing and fostering an internal culture where quality systems are valued, and where standard operating procedures are clearly outlined for staff members will greatly enhance the level of quality within facilities.

Through addressing a wide variety of the challenges that quality assurance executives face in maintaining regulatory compliance within manufacturing facilities, this conference program will create a unique opportunity for networking and knowledge share for forward thinking pharmaceutical executives. Having an opportunity to discuss in an informal and private setting, the challenges in maintaining quality, and understanding what peer executives would do in particular situations will be of tremendous value to manufacturers in attendance.

DISTINGUISHED PRESENTERS INCLUDE:

Steve Niedelman
Former Deputy Associate Commissioner for Regulatory Affairs
FDA
Consultant to FDA and Life Sciences Team
KING & SPALDING

Mide Kraja
Operational Excellence Manager
GENENTECH

Judith Santos
Senior Manager, Document Control and Archiving, Regulatory Affairs
ACORDA THERAPEUTICS, INC.

Peter G. Amanatides
Vice President, Quality Assurance & Quality Control
NOVEN PHARMACEUTICALS, INC.

Robert Castelucci
VP Global Quality Assurance
VERTEX PHARMACEUTICALS

David Dodsworth
Senior Manager, Quality Assurance
AUXILIUM PHARMACEUTICALS

Deva H. Puranam MS, MPhil, MBA
Global Director of Quality
THERMO FISHER

Joseph A. Horvath, PhD
Senior Director, Quality Systems
MILLENIUM: THE TAKEDA ONCOLOGY COMPANY

Manohar Katakam, PhD
Vice President, Manufacturing and Supply Chain
ONCONOVA THERAPEUTICS, INC

Mayo Pujols
Executive Director, Technical Operations
MERCK

Stephen Shields
Director, Worldwide Quality Assurance, Computer Systems Compliance and Quality
ALLERGAN, INC.

Lara Wilt
Site Director, Quality and Compliance
ENDO PHARMACEUTICALS

Brett Merrill
Quality Assurance Supervisor
GLAXOSMITHKLINE

Gerald Zemble
Senior Manager, Quality Engineering
PURDUE PHARMACEUTICALS

Darren Dasburg, PE, MBA
Vice President, Manufacturing
MEDIMMUNE

Karunakar Sukuru, RPh, PhD
Director-Pharmaceutical Technology & Analytical Services
ENDO PHARMACEUTICALS

Melissa Gilmore
Senior Counsel
MCQUIREWOODS LLP

Julie Thomas
Director Quality Affairs
SPINAL RESTORATION BIOLOGICS

Robert Sturm
Director, IT Validation
Formerly with ELAN PHARMACEUTICALS
DAY ONE / MONDAY, MAY 20
2ND ANNUAL QA IN PHARMACEUTICAL MANUFACTURING / MAY 20-21, 2013 / ALEXANDRIA, VA

7:30 REGISTRATION & CONTINENTAL BREAKFAST
8:30 CHAIRPERSON’S OPENING REMARKS
8:40 ROUNDTABLE DISCUSSION: FORWARD THINKING STRATEGIES WHEN BUILDING AND IMPLEMENTING QUALITY SYSTEMS

Implementing a culture of quality from top down throughout the pharmaceutical manufacturing process and building an environment stressing the importance of quality systems will lead to manufacturing excellence and sustainability. Designing clear and rigorous systems that are easily communicated to employees assures a landscape of quality, meeting FDA requirements and standards. Initiating, reviewing, updating and training efficient quality systems ensures necessary SOPs are in place to meet regulatory expectations and compliancy manufacture products.

- Steps taken in building robust quality systems
- Tactics of ensuring quality to avoid consent decrees
- Aligning SOPs and CAPAs to prevent deficiencies
- Meeting FDA heightened regulatory expectations

Steve Niedelman, KING & SPALDING FORMERLY WITH THE FDA

Peter G. Amanatides, NOVEN PHARMACEUTICALS, INC.
Judith Santos, ACORDA THERAPEUTICS, INC.
David Dodsworth, AUXILIARY PHARMACEUTICALS

9:30 CASE STUDY: CONSTRUCTING RISK MANAGEMENT IN THE QUALITY SYSTEM

Establishing risk management allows manufacturers to identify foreseeable pitfalls to avoid in forecasting quality procedures. Installing and regularly reviewing risk management systems ensures that a company stays within appropriate risk levels, while meeting regulatory quality expectations. Mitigating quality manufacturing risks helps pharmaceutical companies build best practices when expanding product capacity and ensuring quality standards are met.

- IntegratingICH Q9 and ICH Q10 at each level of manufacturing
- Clear communication of risk strategies to employees
- Steps taken to properly build and manage risk in the quality system

Joseph A. Horvath, Ph.D., Senior Director, Quality Systems

MILLENIUM: THE TAKEDA ONCOLOGY COMPANY
Robert Castellucci, VP Global Quality Assurance

VERTEX PHARMACEUTICALS

10:30 COFFEE AND NETWORKING BREAK

11:00 CASE STUDY: FRESH APPROACHES TO INSTALLING CAPA PLANS AND ROOT CAUSE ANALYSIS TO ENSURE QUALITY

Efficiently building standard operating procedures and quality systems in the beginning stages of manufacturing guarantees companies are proactively preparing for regulatory inspections. Developing corrective action, preventative action plans (CAPA) ensures a company has a dependable risk management system in place to advantageously influence manufacturing process yielding. Shredding light on innovative tactics to assist in building a culture of quality throughout a manufacturing plant will streamline safety and effectiveness while successfully bringing a product to market.

- Benefits of developing CAPA plans in early stages of manufacturing
- Optimizing manufacturing outcomes through preventative plans
- Enhancing environment of quality by correcting internal discrepancies

Gerald Zembile, Senior Manager, Quality Engineering

PURDUE PHARMACEUTICALS

11:50 GLAXOSMITHKLINE’S INNOVATIVE GMP EMPLOYEE TRAINING TECHNIQUES TO INCREASE QUALITY ASSURANCE

Ingraining a quality mindset throughout the day-to-day manufacturing procedures assists in meeting quality objectives and reassures expectations are properly communicated to employees. A site could be audited by regulatory bodies at any time and as such manufacturers need to prepare through regular employee training, spontaneous internal audits and reviewing functionality of quality systems. Properly training employees creates workplace safety resulting in an environment of quality and aids in preventing warning letters, fines and recalls that waste company time and resources.

- Strategies to ensure employees are following SOPs and quality systems
- Insightful training procedures to guarantee environment of quality
- Optimally conducting unscheduled internal audits in preparation for FDA
- Building quality assurance in the work environment

Brett Merrill, QA Supervisor

GLAXOSMITHKLINE

12:40 LUNCHEON FOR ALL CONFERENCE ATTENDEES

2:00 ENSURING QUALITY COMPLIANCE OF SUPPLY CHAIN PEDIGREE THROUGH INTERNAL AUDITS

Conducting robust internal quality inspections proactively prepares pharmaceutical organizations for regulatory audits while strengthening drug management as a product transitions through the supply chain. Thoughtful approaches to better understanding how to meet the evolving regulatory environment ensures the drug manufacturing process is upholding quality standards. Evaluating the daily practices of a plant and correcting possible inconsistencies not meeting quality standards equips manufacturers to be ready for unexpected FDA audits and ensures quality systems are in place.

- Vigorous root cause analysis and CAPA implementation to compliancy resolve discrepancies
- Optimally enhancing 483 and warning letter prevention
- Best practices of successfully running an internal audit program

Julie Thomas, Director, Quality Affairs

SPINAL RESTORATION BIOLOGICS

2:50 INSIGHT ON GMP DETECTION, PREVENTION AND EXPEDIENT CORRECTION OF HUMAN ERROR

Understanding potential human error within pharmaceutical manufacturing is essential to designing rigorous quality systems and root cause analysis for discovering and correcting foreseeable problems in the supply chain. As regulators are increasing expectations for pharmaceutical manufacturing quality excellence to assure consumer safety, companies must develop clearly written and functional quality procedures. As human error has been the recent cause to several high profile product catastrophes resulting in warning letters, consent decrees and recalls, it is imperative plant managers closely document errors that occur, the investigation and resolution.

- Importance of installing robust CAPA and root cause analysis plans
- Creative tactics for making GMP training interesting and effective
- Novel approaches for meeting regulatory requirements and preventing human errors
- Impact of human error on drug quality and recent errors in GMP

Mide Kraja, Operational Excellence Manager

GENENTECH

3:40 COFFEE AND NETWORKING BREAK

4:00 MERCK’S TECHNICAL OPERATIONS PLAYBOOK: DRIVING CONSISTENCY, REDUCING DEVIATIONS AND ENABLING GROWTH

This case study will give a close look at the tangible steps Merck took to empower robust partnerships with business units and customers to innovatively implement technical solutions that led to the improvement of quality operations. Five manufacturing sites throughout the US and internationally have developed sigma tools that have successfully reduced discard, optimally achieved targets and increased simplicity in the manufacturing process. Through examining the challenges and hurdles Merck faced to optimize outcomes, in attendees will gain a thorough understanding of available opportunities and are invited to openly ask questions to gain further insight.

- Steps taken to implement solutions and improve quality standards
- Impact on industry and Merck’s manufacturing processes
- Overall impact on US, France and Netherland sites

Mayo Pujols, Executive Director, Technical Operations

MERCK

4:50 CASE STUDY: UTILIZING RISK MANAGEMENT WITHIN IT VALIDATION TO IMPROVE GMP SOFTWARE QUALITY

The pharmaceutical industry is constantly evolving as it adopts new technologies in the manufacturing process and companies face the challenge of ensuring that their computer software validation processes are meeting the required 21 CFR Part 11 guidelines and CAPA policies. The FDA suggests using risk to determine the extent of the software validation and CAPA policies. The FDA suggests using risk to determine the extent of the software validation and CAPA policies.

- Determine if manufacturing software system falls under regulations requiring validation
- Evaluate and identify the risk level of GMP system and change needed
- Necessary validation documents and scope of the test scripts
- Risk management materials, URLs and book references

Robert Sturm, Director, IT Validation

FORMERLY WITH ELAN PHARMACEUTICALS

5:40 CLOSING REMARKS AND END OF CONFERENCE DAY ONE
Melissa Gilmore, Stephen Shields,
• Takeaways from receiving excellent & unfavorable regulatory feedback
• Regular validation, quality employee training and internal inspections

Evolution of heightened regulatory expectations have led manufacturers to develop stringent and novel approaches to advantageously prepare for audits and inspections by all regulatory bodies. Innovatively preparing for audits and ensuring quality systems in place are adhered to by all manufacturing employees is essential to receiving favorable inspections and avoiding warning letters. Developing strong quality systems that harmonize regulatory expectations assists in enhancing audit readiness and understanding what bodies emphasize during inspections.
• Grasping the increased global GXP regulations
• Building impressive and compliant quality systems
• Conducting effective supplier audits to preventatively correct problems
• Productively combining systems in place to strengthen audit preparation

Steve Niedelman, Former Deputy Associate Commissioner for Regulatory Affairs, FDA
Consultant to FDA and Life Sciences Team

KING & SPALDING
9:50 UTILIZING QUALITY ASSURANCE TO DEVELOP RIGOROUS POST MARKET SURVEILLANCE

Ensuring the shelf life of a product meets the quality expectations and guidelines from regulatory bodies is crucial to the success of the product life span and optimizing profitability. Cutting corners in the manufacturing process to reduce timelines while cutting costs does not guarantee a quality product is produced and may result in time and money fixing problems once a product is on the shelf. Developing strong post market surveillance to closely monitor a drug helps to guarantee consumers are safe, the product is meeting quality standards and as a result the pharmaceutical company remains reliable in the eyes of the public.
• Inventive strategies to strengthen product shelf life
• Cost effectively reduce timelines without jeopardizing quality
• Steps taken to build post market surveillance & maintain integrity
• Research companies known for doing good post market surveillance

Deva H. Puranam MS, MPhil, MBA, Global Director of Quality
THERMO FISHER

10:40 COFFEE AND NETWORKING BREAK

11:00 A YEAR IN REVIEW: LESSONS LEARNED THROUGH COMPLIANT HANDLING OF PRODUCT RECALLS

In light of recent high profile recalls, all manufacturers from small and large companies alike need to develop a robust plan of action for handling unfavorable feedback from the FDA resulting in a plant closing or product recall. Installing an environment of quality that assures sterility, non-contamination and safety for the consumer is essential. Pharmaceutical companies must have procedures in place to efficiently and expediently correct instances when the manufacturing systems do not meet quality standards, jeopardizing product integrity and possibly harming the general public. This discussion will not only review recent national and global product recalls but provide necessary steps to lucratively correct errors in product manufacturing and optimally prevent future recalls.
• Reviewing current and recent cases of product recall
• Weighing financial impact and liability of product recalls
• Collaboratively working with all stakeholders

Melissa Gilmore, Senior Counsel
MCQUIREWOODS LLP

11:40 ROUNDTABLE DISCUSSION: ACHIEVING QUALITY EXPECTATIONS IN HEIGHTENED REGULATORY LANDSCAPE

Regularity ensuring a company conforms to quality GMP while improving quality systems assists in meeting the increasing regulatory expectations required of pharmaceutical companies. Remaining informed on escalating requirements from the regulatory bodies will assist manufacturers in compliantly producing pharmaceuticals. This discussion will allow executives to discuss real time examples of steps taken to meet requirements of regulatory bodies while providing in-depth question and answer for all attendees.
• Novel approaches to successfully meet heightened regulatory standards
• Regular validation, quality employee training and internal inspections
• Take-aways from receiving excellent & unfavorable regulatory feedback

Stephen Shields, ALLERGAN, INC.
Melissa Gilmore, McQuirewoods LLP
Karunakar Sukuru, RPh, PhD, Endo Pharmaceuticals

WHO SHOULD ATTEND:
Executives that will find this program of greatest relevance are those currently working to ensure quality assurance within their pharmaceutical and biotech manufacturing process. Job titles of executives that will be most applicable for this program include VPs, Directors and Managers of:
• Quality Assurance
• Quality Systems
• Manufacturing Quality Control
• Quality Specialists
• Product Quality Development
• Quality Engineering
• Regulatory Affairs
• Compliance
• Internal Controls and Audits
• GMP
Steve Niedelman
Former Deputy Associate Commissioner for Regulatory Affairs
FDA
Consultant to FDA and Life Sciences Team
KING & SPALDING

Mr. Niedelman retired from the Food and Drug Administration in 2006 after a 34-year distinguished career, where he served as the Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs. He ensured consistent interpretation of FDA’s regulatory policies by directly overseeing offices at the headquarters of the Office of Regulatory Affairs (ORA), including the Office of Regional Operations, Office of Enforcement and Office of Criminal Investigations. Additionally, Mr. Niedelman assisted in the day-to-day management of FDA’s nearly 3,400 field staff responsible for investigative and laboratory operations.

Steven Niedelman serves as lead quality systems and compliance consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters involving industries regulated by the U.S. Food and Drug Administration. He provides strategic advice, insight and guidance to the medical device, pharmaceutical, bio- technologies and food industries to ensure compliance with the requirements of the federal Food, Drug and Cosmetic Act.

Darren Dasburg
Vice President, Manufacturing
MEDIMMUNE

Brett Merrill
Quality Assurance Supervisor
GLAXOSMITHKLINE

Joseph A. Horvath, Ph.D
Senior Director, Quality Systems
MILLENNIUM: THE TAKEDA ONCOLOGY COMPANY

Keynote Conference Speakers:

Pervious AttendeeS Include:

VP, Corporate Regulatory & Quality Science, Abbott
Division VP, Quality & Compliance, Abbott
Associate Director of Quality, Alcon
Quality Manager, Document Control, Alexion Pharmaceuticals
WWQA Director of Computer System Quality, Allergan
Senior Quality Assurance Manager, Allergan
VP, Quality & Head of Regulatory, Amarin Pharmaceuticals
Vice President of Quality, Applied Biologics
Director of Quality Assurance, ApoCell, Inc.
Quality Assurance Compliance, Apotex
Associate Director of Quality Assurance, Arena Pharmaceuticals
Supervisor, Quality Assurance, ARCAD Pharmaceuticals, Inc.
Sr. QA Associate, Astellas
Manager, Quality Assurance, Auxilium Pharmaceuticals
Global VP, Quality Systems & Compliance, Banner Pharmacaps
Director of Quality Assurance, Banyan Biomarkers
Head of Quality Assurance, BIND Biosciences
QA Director, Boehringer-Ingelheim
Director of Global, Quality & Regulatory Compliance, Bristol-Myers Squibb
Director of Quality Systems & Information, Cangene Corp
Manager of Quality Assurance, Capsugel
Director of Global Quality Systems, Celgene Corporation
Senior Director of Quality Assurance, Daiichi Sankyo
Vice President of Quality Assurance, Davia Pharmaceuticals
Director of Quality Control, Elan Pharmaceutical
Director of Supply Chain, Eli Lilly
QA Specialist, Endo Pharmaceuticals
Director of External Quality Management, Fougara Pharmaceuticals
Head, External Quality, Validation & QE, Genentech
Senior Manager Pharmaceutical MFG, Gilead Sciences Corp
Senior Director of Quality Assurance, Healthpoint Biotherapeutics
Manager of Sterile Production, Hi-Tech Pharmaceuticals
Quality Assurance Training Supervisor, Human Genome Sciences
Head of Quality, Brisbane, Ipsen US
Director of Quality Assurance, Janssen
Senior Director of Manufacturing & Process Development, Lux Biosciences
Director of Quality Systems, MAP Pharmaceuticals
Director of Quality Compliance, Medicis
Corporate Manager of Global Quality Management Systems, Merck
Quality Assurance Auditor, Merck
Director of QA & Quality Control, Millennium Pharmaceuticals
Director of Operations & Quality, NDI Medical
VP, Quality Assurance & Regulatory Affairs, Neopharm Pharmaceuticals
Executive Director - Global Quality Operations, Novartis
Executive Director, Quality, Novavax
VP of Quality Assurance, Noven Pharmaceuticals
Director of Compliance, Nycomed US
Senior Manager, Quality Assurance Services, Perrigo Company
Senior Vice President of Quality, Progenics Pharmaceuticals
Senior Manager, Quality Engineering, Purdue Pharmaceuticals
Director, Quality Assurance, Qualltest Pharmaceuticals
Associate Director of Quality Assurance, Reata Pharmaceuticals
Manager of Quality, Sandoz Quality
QA Associate Director, Shire HGT
Director of Quality Assurance, Sorin Group
Director of Quality Management Systems, Takeda Pharmaceuticals
VP, Global Manufacturing, Outsourced Operations, The Medicines Company
Senior Director, Quality Units, Valeant Canada
Senior Quality Assurance Specialist, Vertex Pharmaceuticals
Manager, QA Auditing, ViroPharma Incorporated
Combinations QA Manager, Vistakon

FOR FURTHER EDUCATIONAL OPPORTUNITIES, REGISTER FOR THE FOLLOWING Q1 WEBINAR:

Training Pharmaceutical Quality Assurance Teams for Success
Tuesday, April 9 / 1 P.M. EST
Presented By:
Tim Gillum, PhD, Senior Manager, Training
Baxter Healthcare
Kery Mortenson, Training Effectiveness Manager
Baxter Healthcare
Register now at www.q1productions.com/wb7015.php